December 15, 2023

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1220 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA) – Proposed Rule, 88 *Federal Register* 74712 (October 31, 2023), Docket No. EPA-HQ-OPPT-2020-0642

Dear Administrator Regan:

The Trichloroethylene Panel of the American Chemistry Council (ACC) submits the enclosed comment on the proposed regulation of trichloroethylene (TCE) under the Section 6 of the Toxic Substances Control Act (TSCA). ACC's TCE Panel represents companies interested in the use of the best available science in developing regulation of TCE and is deeply concerned about several aspects of the Agency's proposed risk management rulemaking. As described below, ACC's Panel recommends that the proposed risk management rule for TCE be revised to –

- Heed the recommendations of EPA's scientific advisors and abandon consideration of animal studies suggesting fetal cardiac defects and autoimmunity in fashioning regulatory controls for TCE,
- Establish a regulatory approach that is realistic, practical, transparent, and enforceable for those conditions of use allowed beyond 1 year,
- Remove controls on pretreatment, treatment, and POTW discharge of wastewater containing TCE from remediation projects,
- Remove the phaseout schedule for reactant use of TCE in the manufacture of HFC-134a in lieu of the phase down schedule specified in the American Innovation and Manufacturing Act,
- Delete the prohibition or phaseout of the reuse of TCE generated as a byproduct in the production of other chlorinated organic substances,
- Extend the phaseout schedule for conditions of use requiring more time to identify and implement alternatives, and
- Establish a de minimis exclusion for the use of products containing less than 0.5 % TCE from the proposed controls.

In addition to the enclosed comments, the TCE Panel supports the comments of ACC. Please feel free to contact me at srisotto@americanchemistry.com or at 202-249-6727 if you have questions or wish to discuss the enclosed information.

Sincerely

Steve Risotto

Stephen P. Risotto
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Chemical Products and Technology Division

Enclosure

Comments of the TCE Panel of the American Chemistry Council
on the Regulation of Trichloroethylene
under the Toxic Substances Control Act
88 *Federal Register* 74712
(October 31, 2023)

I. Executive Summary

EPA's proposed risk management rule for trichloroethylene (TCE) would prohibit most uses of the substance within 1 year, but allow ongoing use for a handful of applications for a specified period of time ranging from 2 to 50 years. Owners or operators engaged in a condition of use (COU) beyond the 1-year prohibition would be required to implement a workplace chemical protection program (WCPP) aimed at achieving a proposed existing chemical exposure limit (ECEL) of 1.1 parts per billion (ppb). The proposed ECEL is based on the Agency's assessment of developmental effects reported in a controversial set of laboratory animal tests from a single group of researchers that have not been duplicated by any other laboratory. In recognition of the concerns about the significance of the developmental effects, EPA has identified an alternative regulatory proposal using an ECEL of 4 ppb that relies on reports of immune effects in a single laboratory study despite conflicting evidence in other better-conducted studies.

In the Preamble of the proposal, EPA acknowledges that both the proposed and alternative ECELs are below the limit of detection (LOD) of established analytical methods[1] and requests comment on two alternative approaches – either (1) establishing the LOD as an "interim exposure limit" or (2) requiring owners/operators to reduce exposures to meet the ECEL "to the extent possible." Neither of these suggested approaches, however, would be practically enforceable. Accordingly, EPA should abandon the proposal to set an ECEL and instead specify realistic, practical, transparent, and enforceable methods for reducing exposures for those COUs that would be permitted beyond the initial 1-year phase-out period.

EPA has identified several COUs that require the use of TCE for a longer period of time due to the absence of available alternatives, their importance to the national economy or national security, and/or compliance with requirements of other EPA programs. However, the time frames proposed for some of the COUs do not appear adequate for the development of viable alternatives or have the potential to conflict with other regulatory requirements. Moreover, the proposal to require implementation of a WCPP for entities involved in the disposal of TCE-contaminated water to pre-treatment, treatment, or a publicly owned treatment works (POTW) is impractical and unnecessary. In addition, reuse of TCE produced as a byproduct in the manufacture of other chlorinated organics should not be subject to prohibition or phaseout.

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[1] 88 *Fed. Reg.* 74738.

II. EPA Overstates the Risks of Exposure to Trichloroethylene

In its 2020 Risk Evaluation for TCE, EPA relied on a report of immunosuppression autoimmunity in a drinking water study in laboratory mice for its risk determinations, despite contradictory evidence from a better conducted inhalation study in rats.[2] The TCE Risk Evaluation also reviewed the evidence for developmental effects (*i.e.*, fetal cardiac defects) in laboratory tests, but concluded that large uncertainties in dose-response and extrapolation of the data precluded their use in making a risk determination. This conclusion regarding fetal cardiac defects was reinforced during peer review by both the Agency's own Science Advisory Committee on Chemicals (SACC)[3] and the National Academies of Science, Engineering and Medicine (NASEM).[4] Yet in its risk management proposal, EPA indicates that reliance on cardiac defects is now "scientifically valid"[5] without providing any additional scientific justification. Acknowledging that scientific support for this conclusion may not be as strong as the Agency suggests, it proposes a regulatory alternative that relies on the autoimmunity endpoint selected in the TCE Risk Evaluation. As described below, the use of developmental effects to set the ECEL is not scientifically supported and should be removed from the proposal as well as any discussion of benefits achieved from reduced risk of fetal cardiac defects resulting from reduced TCE exposure.

a. EPA Ignores the Recommendation of its Scientific Advisors Regarding Developmental Effects

EPA specifically requests comment on "the use of the more sensitive developmental toxicity endpoint to inform TCE risk management decisions,"[6] noting that it received numerous comments on the endpoint selection in its TCE Risk Evaluation raising "concerns pertaining to political interference and scientific integrity."[7] Yet EPA fails to acknowledge the extensive scientific literature and external scientific peer reviews that remove any question about scientific integrity. The decision to rely on reports of fetal cardiac defects from a single laboratory in deriving the proposed ECEL for TCE not only runs counter to the Agency's own conclusions in its TCE Risk Evaluation, but also to the recommendations from the SACC on the evaluation and NASEM's subsequent review of the systematic review process used for evaluating TCE. Three separate studies have been unable to duplicate the results reported in the 2003 publication by Johnson *et al.* (2003)[8] that are the basis for the Agency's proposed ECEL. The results reported by Johnson *et al.*,

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2 USEPA. Risk Evaluation for Trichloroethylene, CASRN: 79-01-6. EPA Document No. 740R18008 (November 2020). (TCE Risk Evaluation)

3 USEPA. TSCA Science Advisory Committee on Chemicals. Meeting Minutes and Final Report No. 2020-4 (2020). EPA-HQ-OPPT-2019-0500-0111 (SACC Report)

4 NASEM. The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations. Washington, DC. The National Academies Press (2021). (NASEM Report)

5 88 *Fed. Reg.* at 74731

6 Ibid, at 74723.

7 Ibid.

8 Johnson PD *et al.* Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat. *Environ Health Perspect* 111: 289-292 (2003).

moreover, were rejected by a National Research Council (NRC) committee convened by EPA in 2006,[9] and the study was considered to be of "low confidence" by the majority of EPA scientists who reviewed it in 2014.[10] The Agency's continued disregard of the best available science and the advice of its own peer reviewers based on the unsubstantiated allegations of bias violates the scientific standards mandated in TSCA Section 26.

Among the charge questions developed by the Agency for the SACC's review of the draft TCE Risk Evaluation was a specific request to comment on the "weight of evidence (WOE) analysis approach and conclusions for [fetal heart malformations]."[11] In response, the majority of the 27 standing and *ad hoc* members of the SACC agreed that the limited evidence for fetal heart malformations should not be used for the purposes of quantifying risks. In its report to the Agency, the SACC identified a number of concerns with the draft TCE Risk Evaluation's analysis of the health endpoint, noting that the scoring of results for cardiac effects was "overly simplistic, difficult to understand, and problematic in its value judgments and net result."[12] The Committee also concluded that –

> Johnson *et al.* (2003) has inadequate reporting of methods used. Use of non-concurrent, pooled controls per the TSCA scoring definition for this metric meets the TSCA definition of "Unacceptable for Risk Assessment." [13]

Importantly, the SACC recommended that the Agency "revise and expand" its justification for not using fetal heart malformations for its risk determination, but did not challenge the decision to use another health endpoint.

The subsequent review of the final TCE Risk Evaluation by the NASEM committee charged with reviewing the TSCA systematic review process revealed that the problems identified by the SACC had not been corrected. The committee concluded that the lack of a documented process to explain deviations from standard practice greatly impacts the transparency of the evidence integration for fetal heart defects. In particular, the committee noted that the use of two different methods within the evidence integration step (mathematical average, semi-qualitative grouping) is troubling and "runs completely counter" to published Agency guidance."[14] The committee also noted that the evaluation of the cardiac endpoint "conflated aspects of important systematic review elements: evaluating individual studies, a body of evidence (*i.e.*, strength or certainty of evidence for a conclusion), and a level of confidence in a recommendation or determination of causation."

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[9] NRC. Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues. Washington, DC: The National Academies Press (2006). (NRC Report)

[10] USEPA. TCE developmental cardiac toxicity assessment update (undated). (Document ID EPA-HQ-OPPT-2012-0723-0045)

[11] SACC Report, at 63.

[12] Ibid, at 66.

[13] Ibid, at 63.

[14] NASEM Report, at 49.

The concerns expressed by the SACC and the NASEM committee are similar to those voiced by the NRC committee reviewing the draft assessment of TCE for the Integrated Risk Information System (IRIS) in 2006. The NRC committee noted that –

> the rodent studies showing trichloroethylene-induced cardiac teratogenesis at low doses were performed by investigators from a single institution. Also noted were the unusually flat dose-response curves in the low-dose studies from these investigators. . . Thus, the animal data are inconsistent, and the apparent species differences have not been addressed.[15]

The NRC committee concluded that "[t]he results need to be replicated in another laboratory to clarify the dose-response relationship."[16] Yet, despite the absence of cardiac defects in two subsequent well documented laboratory studies – an inhalation study published later in 2006 and a drinking water study in 2020 – EPA continues to cite the findings of the single study group. The Agency's changing rationales for its conclusions – ranging from differences in exposure route[17] to genetic drift[18] to the inferiority of the Agency's approved dissection method[19] – are not credible. Furthermore, there is no evidence from epidemiology studies that TCE exposure can lead to fetal cardiac malformations.[20]

The Preamble is not transparent about any of these issues. It fails to disclose that every peer review of the evidence for fetal cardiac defects has concluded that the results are of low confidence and are not appropriate for risk assessment. These peer reviews include the 2006 review of EPA's draft IRIS assessment, an internal review by Agency scientists, and the reviews of the TCE Risk Evaluation by NASEM and EPA's own SACC. It is misleading and inappropriate to reference comments suggesting "political interference" in support of its conclusion when the Agency has failed to convince a single group of "reasonable scientists" that the fetal cardiac defects should be the basis of the Agency's assessment of non-cancer effects of TCE. Since EPA has not demonstrated the relevance of fetal cardiac deformation, this endpoint should be removed from consideration in this risk management proposal including its used in setting an ECEL and in any cost-benefit analysis.

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15 NRC Report, at 171.

16 Ibid, at 5.

17 USEPA. Toxicological Review of Trichloroethylene (CAS No. 79-01-6): In Support of Summary Information on the Integrated Risk Information System. EPA/635/R-09/011F (2011).

18 Makris SL *et al.* A systematic evaluation of the potential effects of trichloroethylene exposure on cardiac development. *Repro Toxicol* 65:321-358 (2016).

19 TCE Risk Evaluation, at 634.

20 Makris *et al.*, at 327.

b. The Study of Immune Effects Selected by EPA Provides Incomplete and Inconsistent Data

The Agency's primary alternative regulatory proposal relies on the Agency's assessment of immune effects in the study by Keil *et al.* (2009), which reported autoimmunity in laboratory mice exposed to TCE in drinking water.[21] The Docket for the TCE Risk Evaluation contains several comments highlighting the limitations of the study by Keil *et al.*[22] While the study was considered of high quality according to EPA's systematic review, the public record identifies considerable deficiencies in the exposure characterization that introduce uncertainty in the interpretation of the study findings. In reviewing the data, the SACC also expressed caution about the lack of data on exposures in the Keil *et al.* study[23] and recommended that EPA only consider studies that provide analytical chemistry results confirming exposure.[24]

In addition to methodological concerns, commenters also noted an inconsistent increase in autoantibodies during the treatment period and a lack of dose-response for most time points. The study also reported an inconsistent response between the strains of mice tested. In considering the results, the SACC questioned the significant disparity between the Human Equivalent Concentrations (HECs) calculated from the Keil *et al.* study compared to other studies investigating the immunological endpoint.[25]

A more appropriate basis for assessing immune effects is the study by Boverhof *et al.* (2013)[26] which reported treatment-related effects in conventional assays measuring immunosuppression in rats. The results reported in the Boverhof *et al.* study are consistent with the effects on the immune system reported by Selgrade and Gilmour (2010) which are the basis for EPA's assessment of the acute effects of TCE exposure.[27] Immunosuppression has a different mechanism of action than increase in autoantibodies, the endpoint reported by Keil *et al.* (2009). In addition, the study by Boverhof *et al.* was conducted by a relevant route of exposure (inhalation) and was subject to a rigorous review process.[28]

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[21] Keil DE *et al.* Assessment of trichloroethylene (TCE) exposure in murine strains genetically-prone and non-prone to develop autoimmune disease. *J Environ Sci Health A Tox Hazard Subst Environ Eng* 44: 443-453 (2009).

[22] For example, see comments submitted by the Halogenated Solvents Industry Alliance (HSIA) dated April 27, 2020. EPA-HQ-OPPT-2019-0500-0094. (HSIA Comments)

[23] SACC Report, at 73.

[24] Ibid, at 17.

[25] Ibid, at 72.

[26] Boverhof DR *et al.* Assessment of the immunotoxic potential of trichloroethylene and perchloroethylene in rats following inhalation exposure. *J Immunotoxicol* 10: 311-320 (2013).

[27] Selgrade MK Gilmour MI. Suppression of pulmonary host defenses and enhanced susceptibility to respiratory bacterial infection in mice following inhalation exposure to trichloroethylene and chloroform. *J Immunotoxicol* 7: 350-356 (2010).

[28] HSIA Comments, at 19.

III. The Proposed Exposure Limits are Impractical and Should be Deleted

The proposed ECELs of 1.1 and 4 ppb are 4 to 5 orders of magnitude below the current permissible exposure limit (PEL) of 100 parts per million (ppm) enforced by the Occupational Safety and Health Administration (OSHA) and 2500 times (or more) lower than the threshold limit value (TLV®) of 10 ppm recommended by the American Conference of Governmental Industrial Hygienists (ACGIH). In fact, the ECELs are well below any occupational exposure limit established internationally.[29]

Moreover, EPA's analysis indicates that the proposed limits are below the LOD of current analytical techniques. It is not clear how an owner/operator engaged in one of the permitted COUs would demonstrate compliance as part of the required WCPP. Recognizing this challenge, the Agency has requested comment on two alternative approaches to reduce exposures. Because neither approach is practical EPA should instead develop an alternative, technology-based approach that relies on demonstrated techniques for controlling exposures instead of establishing a regulatory limit.

a. The Proposed Limits Cannot be Reliably Measured with Current Analytical Methods

EPA's risk management proposal would require owners/operators in a COU allowed to continue beyond the initial 1-year phase-out period to implement a WCPP to demonstrate compliance with the proposed ECEL of 1.1 ppb. The proposal would additionally require facilities to conduct periodic exposure monitoring if exposure levels exceed an action level of one-half the ECEL, or 0.5 ppb.[30] Notwithstanding the question of whether such low levels can be achieved, there is significant question whether these levels can be reliably measured. EPA acknowledges in the Preamble that the LOD for current personal breathing zone (PBZ) measurements is well above the proposed levels.

While it is possible that analytical techniques will improve over the next few years, there is no guarantee that methods will improve sufficiently to measure the proposed ECEL, or over what period of time such methods will be developed. It is unlikely that an owner/operator would be able to conduct the initial exposure monitoring within the first 6 months following promulgation of the proposal. Without being able to determine whether workers are being exposed above the proposed ECEL (or proposed action level), companies could be forced to abandon use of TCE or to designate all areas of a facility as regulated and require respiratory protection for any individuals entering the facility. Neither option is realistic or practical and both options run counter to the Agency's mandate to consider the availability of alternatives and potential impacts on national defense and the economy in selecting risk management approaches.

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[29] GESTIS – International Limit Values for Chemical Agents. https://limitvalue.ifa.dguv.de/

[30] Under the proposal, monitoring would be required every 6 months if exposures are between 0.5 and 1.1 ppb, until 2 consecutive measurements indicate exposure is below the action level.

b. Application of an Interim ECEL is Unduly Burdensome

In recognition of the inability of an owner/operator to measure exposures down to the proposed ECEL, EPA seeks comment on an approach that would establish the LOD as an interim exposure limit "with a step down to the ECEL at a later date until the applicable prohibition would take effect."[31] The Agency provides no suggestions for how it would determine when a "step down" would be appropriate, but rather seeks comment on "recommendations for one or more incremental exposure values and associated timelines for achieving the incremental exposure levels and the currently proposed ECEL." Moreover, EPA's brief discussion does not address or seek comment on, the burden to industry in complying with an increasingly stringent exposure standard before being required to phase out use of TCE. Such an approach could require an owner/operator to implement additional engineering controls on two or more occasions to achieve an ever-decreasing standard.

c. A Standard Based on Lowering Exposures to the "Extent Possible" is Unenforceable

Elsewhere in the Preamble, EPA seeks comments on ways for owners and operators to "identify the lowest achievable exposure level, what documentation would be needed to support that further reductions are not possible, and whether EPA should provide a definition of meeting the ECEL *to the extent possible*." (emphasis added). Even with clarification of these issues, enforcement of such a subjective standard is impractical and fraught with the potential for challenges regarding interpretation.

d. The WCPP Should be Based on Technology Demonstrated to Reduce Worker Exposure

The concerns expressed by the Agency itself regarding the implementation of its proposal (and primary regulatory alternative), combined with EPA's failure to heed the recommendations of its scientific advisors concerning the health studies selected for establishing the proposed ECELs, demonstrate that the current proposal is neither practical nor based on the best available science. Rather than impose a standard that cannot be met with current methods, with no assurance that sufficiently sensitive methods will be developed, the Agency must abandon its proposal to establish an ECEL for those COUs extending beyond the initial 1-year phaseout. Instead, the Agency should adopt an approach that focuses on available control technology and worker protection techniques. Such an approach could require, in part, -

- ventilation hoods for the use of TCE for laboratory use, and
- site-limited enclosed processes for other COUs, combined with the use of appropriate respiratory protection during short-term maintenance and repair activities.

[31] 88 *Fed .Reg.* at 74738.

The recommended approach to controlling exposures for laboratory use is consistent with the recent proposal for perchloroethylene (PCE).[32] The recommendation for enclosed processes is further explained in ACC's comment on the risk management proposal for methylene chloride.[33] As outlined below, the restrictions should not extend to wastewater treatment from remediation activities as exposures in this scenario are minimal and compliance is impractical.

Implementing a technology-based approach, rather than one based on the proposed ECELs, will simplify compliance and enforcement while minimizing exposures related to those COUs subject to extended phaseout schedules.

IV. EPA Should Not Impose Limits on Pretreatment, Treatment, and Discharge to POTWs

Under the proposal, EPA would prohibit the disposal of wastewater containing TCE for pretreatment, treatment, and to POTWs within 9 months of the rule's promulgation.[34] Disposal of groundwater and other wastewater from remediation projects would be granted a 50-year exemption under TSCA Section 6(g) provided, however, that the affected treatment facilities implement a WCPP aimed at achieving the proposed ECEL. According to the Preamble, EPA believes that the TSCA 6(g) exemption would provide sufficient time for TCE remediation to be completed "at most sites," but requests comment on whether 50 years is a reasonable time frame. As an alternative, EPA has suggested a compliance timeframe of 3 years.[35] The WCPP requirement would extend to all parties involved in the disposal of water from remediation sites.

a. EPA Has Not Evaluated the Costs of Requiring WCPP Implementation at Treatment Operations

The proposal to require all entities engaged in the disposal of wastewater from remediation operations to implement a WCPP has the potential to involve a significant number of operations and individuals. However, EPA has not attempted to estimate the cost of the requirement or even the number of entities potentially affected. In explaining its decision, the Agency notes that -

> EPA did not identify alternative disposal options in the case of disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of cleanup projects of TCE-contaminated groundwater and other wastewater. Approaches used for cleanup of TCE-contaminated water

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[32] 88 *Fed. Reg.* 39652 (June 16, 2023). Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA). Proposed Rule.

[33] https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0465-0268

[34] According to the Preamble, solid waste exceeding the Resource Conservation and Recovery Act (RCRA) regulatory level of 5 milligrams per Liter (5 mg/L) using the toxicity characteristic leaching procedure (TCLP) would remain subject to the requirements of RCRA.

[35] 88 *Fed. Reg.* at 74753

> are specific to the specific circumstances of individual sites and information is not available to determine what those approaches may be.[36]

Although the approach to disposal of wastewater may be specific to the individual site, the number of disposal options is limited and could be reasonably analyzed. Moreover, the number of entities potentially affected by the proposal to require a WCPP could reasonably be estimated based on Agency data and data available from the states.[37] Without an estimate of the potential costs of implementing the proposed requirement, it is impossible to conclude that the proposed restriction is cost effective.

Furthermore, the Agency does not have an appropriate basis for concluding that exposures associated with the treatment of wastewater from remediation operations present an unreasonable risk. While the TCE Risk Evaluation includes information on releases of TCE to surface water from POTWs,[38] it provides no data on worker exposures (inhalation or dermal) at these facilities. Estimates for inhalation exposure at wastewater pretreatment and treatment operations, moreover, are based on monitoring data from TCE repackaging operations.[39] Such extrapolation of the repackaging of neat solvent at a distribution facility is not an appropriate surrogate for wastewater treatment operations where TCE levels will not exceed 5 mg/L, per RCRA requirements.[40] In the absence of a more appropriate estimate of exposure from wastewater treatment, EPA cannot conclude that exposures at these facilities present an unreasonable risk.

b. A 50-Year Exemption for Cleanup Projects is Insufficient

EPA seeks comment on the proposal to phaseout the disposal of wastewater from remediation activities for pretreatment, treatment, and to POTWs after 50 years.[41] In the Preamble, the Agency notes its concern that eliminating the option for treatment of groundwater would be "a significant burden" to cleanups and "would likely slow the pace of remediation at the numerous sites where TCE-contaminated groundwater is a problem."[42] However, the Agency suggests that the 50-year phaseout "would allow a sufficient time for TCE remediation to occur at most sites." EPA provides no information to support this suggestion, nor has it evaluated alternatives to this "common disposal method." ACC's TCE Panel recognizes the challenges in

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[36] USEPA. Economic Analysis of the Proposed Regulation of Trichloroethylene under TSCA Section 6(a). October 2023, at 5-6 (Table 5-2)

[37] EPA's CERCLIS database contains hundreds of sites undergoing cleanup of TCE contamination.

[38] TCE Risk Evaluation, at 295 (Table 4-1).

[39] While pretreatment and treatment are not identified as a COU in the 2020 Risk Evaluation, Table 4-1 of the Risk Evaluation indicates that these operations are included in the exposure scenario identified as "process solvent recycling and worker handling of wastes."

[40] TCE Risk Evaluation, at 307 (Table 4-9). It is not clear what the Agency used as a basis for estimating risk from dermal exposures.

[41] For the primary alternative regulatory action EPA would prohibit treatment of wastewater from remediation after 3 years from promulgation of the rule (88 *Fed. Reg.* at 74761).

[42] 88 *Fed. Reg.* at 74748.

evaluating this issue, particularly as it involves projecting actions well into the future, but notes that the current discussion in the Preamble is inadequate to support the proposed restriction.

In addition, the 50-year exemption does not take into account the potential that new cleanup sites with TCE contaminated groundwater may still be discovered in the future. Each site will need to go through the complete Superfund process, including site investigations to develop a Record of Decision (ROD) that will outline the necessary remediation to be conducted at the site. This process could take 10 to 20 years to complete before remediation even begins.

c. WCPP Compliance for Pre-treatment, Treatment, or at POTWs is Unclear and Unmanageable.

EPA's requirement to develop a WCPP appears to also apply to clean up sites that dispose of TCE. This approach seems unreasonable and unmanageable as proposed. If such a program is to be implemented, the following questions must be addressed –

- Who is responsible for developing the WCPP? If it is the generator of the waste for disposal, this would only cover workers engaged in the remediation activities. Would compliance with a WCPP be necessary if all the work related to a remediation site occurs outside (no treatment building is present)?

- What responsibility does the receiver (POTW, waste hauler, landfill) have to develop and/or comply with a WCPP? The Preamble indicates that owners and operators of the locations where workers are handling TCE wastewater would be responsible to comply with the WCPP.

- Some of the work done at cleanup sites is completed by workers who are collecting samples that can result in the generation of small quantities of waste for disposal. Does the WCPP and associated monitoring apply to these workers? Would any waste haulers or other recipients of TCE purge water need to develop their own WCPP to transport and/or receive this waste?

- Do workers at a cleanup site need to be covered under a dermal protection plan as they are likely to handle TCE contaminated water or soil?

Requiring the development of a WCPP for any activities related to TCE sampling, mitigation, or remediation would place an unmanageable burden on responsible parties conducting cleanup activities. Often the work at a cleanup site happens intermittently and not on a regular schedule. In these cases, it would be difficult to develop any sort of regular monitoring program and responsible parties could be forced to implement sampling every time they are in the field. As stated by EPA, after initial monitoring, periodic monitoring needs to be conducted if there is a change in workplace conditions. As cleanup sites are dynamic systems, this could require monitoring every time a sample is collected or sent to a treatment system. Moreover, at the

unmeasurable ECEL levels currently proposed by EPA, all work at a remediation site would need to be completed using respiratory protection.

Given the challenges with EPA's current proposal, there is a concern that waste haulers, POTWs, or other receivers of TCE contaminated wastewater may simply refuse to accept these materials as the requirements for compliance are too complicated and cumbersome. For example, if truck drivers that pick up TCE waste need to comply with a WCPP, this would require sampling at every pick-up location as the "workplace conditions" would change at every location. Such an approach is not feasible to allow remediation activities to continue at a reasonable pace.

Finally, it should be noted that TCE is rarely found alone at cleanup sites, but is usually one of several volatile organic compounds (VOCs) present. Under EPA's proposed rule, disposal of any groundwater that contains any amount of TCE would be required to comply with the requirements of this regulation. Indeed, all receivers of groundwater from cleanup sites would be forced to assume that TCE is present, since it is not currently possible to measure down to the ECEL. This approach is not practical nor feasible for the thousands of federal and state cleanup sites currently undergoing active remediation. EPA's proposed approach would only complicate an already complex process, result in significant delays to remediation of cleanup sites, and contravene EPA's mission to protect public health and environment.

At many cleanup sites, workers are required to have OSHA Hazardous Waste Operations and Emergency Response (HAZWOPER) training to be on-site, to collect samples and to conduct remediation activities. The HAZWOPER training ensures that individuals in the field understand the potential hazards associated with their work activities and that they take sufficient precautions to limit exposures to chemicals in the field. This program has been successfully implemented at thousands of clean-up sites and should continue to be used instead of the WCPP and ECEL process proposed by EPA.

d. EPA Must Clarify that Certain Cleanup Activities are Excluded from this Regulation.

Cleanup sites use a wide variety of technologies and approaches to remove TCE from contaminated media. These ex-situ options include pump and treat, air stripping, carbon treatment, soil vapor extraction [SVE], sub-slab depressurization systems [SSDS], excavation, incineration, and off-site disposal and are designed to remove TCE from contaminated media including soil, water (groundwater and surface water) and vapor (soil vapor and indoor air). Should EPA proceed to include disposal in the regulation, it must clarify that, other than disposal of groundwater for pretreatment, treatment, and to POTWs, no other remedial actions at cleanup sites will be covered or affected. Therefore, if TCE is released to the air via a SVE or SSDS, it will not be necessary to do any monitoring or comply with a WCPP. If EPA were to apply this regulation to other cleanup technologies, this will significantly increase the burden for site cleanup for homeowners, businesses and responsible parties.

V. EPA Should Delete the Timeline for Phaseout of TCE Use in the Production of HFC-134a in Lieu of Other Statutory Requirements

EPA proposes to phaseout the use of TCE as an intermediate in the production of hydrofluorocarbon (HFC) 134a over 8.5 years (by Spring 2033),[43] while requiring that facilities implement a WCPP during the phase-out period. The additional time allowed for this COU recognizes the importance of reducing HFCs to the Agency's climate protection efforts and the transition away from these substances required under the American Innovation and Manufacturing (AIM) Act. However, the proposed phase-out schedule does not align with the schedule developed in the regulations implementing the AIM Act requirements. As noted in Table 1, EPA's proposed phaseout for TCE in HFC-134a would occur in advance of the phase-down schedule for HFCs overall.

Table 1. HFC Phasedown Schedule and Consumption & Production Allowance Caps Under the AIM Act[44]

Years	Allowance Cap (as a percentage of Baseline)	Production (MMTEVe)	Consumption (MMTEVe)
Baseline	100	382.55	303.89
2023	90	344.3	273.5
2024-2028	60	229.5	181.5
2029-2033	30	114.8	90.8
2034-2035	20	76.5	60.5
2036 & after	15	57.4	45.4

MMTEVe – million metric tons of exchange value equivalent

a. The AIM Act Imposes Clear Criteria for the Phaseout of HFC-134a Manufacture

The phase-down schedule developed to implement the requirements of the AIM Act balances the mandate to reduce the production of HFCs with the need to smooth the transition to substances with lower global warming potential (GWP) and to maintain existing equipment. The AIM Act schedule is based on the schedule included in the Kigali Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer that was ratified by the United States on October 31, 2022. In addition to setting an overall cap on production and consumption, the regulation assigns caps to individual companies including those companies using TCE to produce HFC-134a.

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[43] The Agency's Spring 2023 regulatory plan calls for finalization of the TCE rule in October 2024. The phaseout of 8.5 years would therefore end in April 2033. The primary regulatory alternative would extend the phaseout to 9.5 years, or by April 2034.

[44] 88 *Fed. Reg.* 46836, July 20, 2021. Phasedown of Hydrofluorocarbons: Allowance Allocation Methodology for 2024 and Later Years. The allowances apply to 18 of the most commonly used HFCs, including HFC-134a, with exchange values ranging from 53 to 14,800. The value for HFC-134a is 1,430.

b. The Proposed Phaseout May Result in Potential Conflicts with AIM Implementation

In requiring a phaseout of the use of TCE to produce HFC-134a on a faster schedule than the HFC phase down schedule specified under the AIM Act, the proposal has the potential to disrupt individual company efforts to transition to low GWP substances across a wide range of industry sectors and applications. To eliminate the potential for such disruption, the ACC TCE Panel urges the Agency to remove the phase-out schedule for TCE use in this COU and instead rely on the schedule established under the AIM Act, while requiring the worker protections as outlined elsewhere in this comment.

VI. Reuse and Recycling of TCE Produced as a Byproduct for Processing as a Reactant/Intermediate Should Not be Phased Out

The processes used to manufacture 1,2 dichloroethane (ethylene dichloride, or EDC), PCE and carbon tetrachloride (CTC) have been designed to process and recycle chlorinated streams. In lieu of disposal, the processing and recycling of chlorinated streams allows a manufacturing facility to obtain and utilize the full value of every chlorine molecule processed at a plant. These manufacturing processes unintentionally produce small quantities of TCE as a byproduct that are reprocessed/recycled to create additional product. Any restriction on the reuse of streams that contain TCE unintentionally produced as a byproduct not only creates a significant amount of waste requiring disposal, but would also compromise and potentially shut down highly specialized manufacturing processes and facilities.

In the Preamble, EPA indicates that TCE manufacture does not include the production of TCE as a byproduct, noting the Agency intends to consider such byproduct production as part of the risk evaluation for EDC.[45] The Preamble also indicates that the reuse of byproduct or residual TCE as a reactant is included under the COU identified as Processing as a Reactant/Intermediate[46] However, the proposed regulatory language fails to address the reuse of byproduct TCE and the discussion of the regulation of Reactant/Intermediate COU in the Preamble fails to address the byproduct TCE.

To allow for the ongoing processing and recycling of these critical streams, EPA should clarify/confirm in the final rule that the definition of manufacturing does not include TCE produced as a byproduct. Additionally, the final rule preamble and amended 40 CFR Part 751 should confirm or be modified to address the following processing conditions of use under processing as a reactant:

- TCE unintentionally produced at as a byproduct in the EDC manufacturing process and then reprocessed as a feedstock in the production process is not address in the rule and will be evaluated as part of the risk evaluation of EDC.
- Byproduct TCE processed/recycled as a part of a larger reactant intermediate in the production of PCE and CTC is not subject to prohibition or phaseout provided facilities comply with revised WCPP requirements

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[45] 88 *Fed. Reg.* at 74726

[46] Ibid. The description of the regulatory proposal for the Processing as a Reactant/Intermediate, Table 2 (p. 74759) of the Preamble only refers to a phaseout for TCE use in HFC-134a.

These two clarifications or modifications are needed in the final rule to allow for the continued processing/recycling of streams containing TCE as a byproduct in EDC and the PCE/CTC manufacturing processes. Allowing for recycling in these processes would also align with EPA's proposed regulation of CTC which allows Processing: Recycling in compliance with the WCPP.[47] It is critical that reuse of byproduct TCE as a reactant/intermediate not be subject to phaseout as there are no viable alternatives for the handling of this material and any potential worker exposures during the process are well controlled.

As described below, TCE produced as an unintentional impurity in the chlorinated organics production process can be effectively and efficiently collected and recycled back into the production stream. A phaseout of reuse/recycle of TCE as a reactant during the chlorinated organic manufacturing process would result in the following negative impacts –

- an increase in the quantity of hazardous waste disposed, and associated disposal costs, due to the inability to recycle streams that include TCE as a byproduct;
- an increase in the use of virgin raw material (e.g., chlorine, ethylene) and associated production costs to replace the streams that include TCE as a byproduct that would be prohibited for processing/reuse;
- extensive and costly capital modifications to remove TCE as a byproduct in associated streams; and
- possible shut down of chlorinated organic manufacturing facilities in the United States.

TCE byproduct reuse in the EDC manufacturing process and chlorinated organics process are addressed separately below.

a. Reuse/Recycling of TCE Produced as a Byproduct in the EDC Manufacturing Process

EPA proposes to exclude from the definition of domestic manufacturing (including manufacturing for export) production of TCE as a byproduct, including during the manufacture of EDC, which EPA intends to consider in the upcoming risk evaluation for EDC. The Preamble of the describes domestic manufacture as follows -

> This condition of use refers to the making or producing of a chemical substance within the United States (including manufacturing for export), or the extraction of a component chemical substance from a previously existing chemical substance or a complex combination of substances. This description does not apply to TCE production as a byproduct, *including during the manufacture of 1,2-*

[47] 88 *Fed. Reg.* 49180 (July 28, 2023). Carbon Tetrachloride (CTC); Regulation Under the Toxic Substances Control Act (TSCA). Proposed Rule.

> *dichloroethane*, which EPA intends to consider in the risk evaluation for 1,2-dichloroethane (Ref. 39).[48]

A similar statement about including byproduct TCE production in the EDC risk evaluation is included in the Response to Comments for the TCE Risk Evaluation.[49]

In the EDC production process, TCE is unintentionally produced as a byproduct of the oxychlorination and direct chlorination of ethylene. TCE will always be produced at very low-ppm levels as part of the chemical reaction; the process cannot be altered to prevent the unintentional TCE byproduct formation. In the purification step, the TCE that is produced as a byproduct is present in the heavy ends at levels averaging 0.2% and light ends at levels of 0.13%. These resulting heavy and light end streams from the oxychlorination and direct chlorination manufacturing processes are processed/recycled as a feedstock to manufacture hydrogen chloride gas (HCl) which in turn is used to manufacture additional EDC.

TCE unintentionally produced at as a byproduct in the EDC manufacturing process and then reprocessed in a feedstock to HCl, which is used to manufacture additional EDC (including the EDC feedstock to vinyl chloride where TCE is removed as an impurity and recycled back to the EDC manufacturing process) should be evaluated in the EDC risk evaluation. ACC's TCE Panel emphasizes that the evaluation of TCE byproduct that is produced and reused in this EDC process is well underway in the EDC risk evaluation. Given the consistent statement by the Agency that TCE produced as a byproduct and then reused in the EDC manufacturing process is a subject of the EDC risk evaluation, we request that the final TCE Risk Management Rule expressly confirm and clarify that TCE produced as a byproduct and then reused in the EDC manufacturing process is not covered by this regulation and will be addressed in the EDC risk evaluation.

b. Reuse/Recycling of TCE Produced as a Byproduct in the Manufacture of PCE and CTC Process

The chloromethanes manufacturing process, which produces methyl chloride, methylene chloride, chloroform and carbon tetrachloride via hydro and thermal chlorination, produces TCE as an unintentional byproduct. The heavy-end streams, light-end streams, and crude CTC that result from this process contain unintentional TCE as a byproduct/impurity. Most of the streams from the chloromethane production include an average of 0.9% TCE . A small (<1%) heavy end component includes an average of 1%-3% of TCE. These streams are processed/recycled in a PCE/CTC Reactor to produce these two chemicals.

Select streams from some oxychlorination and direct chlorination EDC manufacturing processes, containing 0.2% TCE, are also processed/recycled in the PCE/CTC Reactor. The final CTC product contains up to 0.01% TCE; the final PCE product contains up to 0.001% TCE. Diluent outlet

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[48] 88 *Fed. Reg.* at 74726. (emphasis added)

[49] USEPA. Summary of External Peer Review and Public Comments and Disposition for Trichloroethylene (TCE); Response to Support Risk Evaluation of Trichloroethylene (November 2022), at 124.

streams from the PCE/CTC Reactor that do not meet final product specifications are recycled back into the PCE/CTC Reactor and contain a concentration of 0.5% TCE.

If the proposed rule is finalized in a manner that prohibits the processing/recycling of streams with TCE byproduct in the PCE/CTC Reactor, that prohibition would have an enormous impact on downstream production and increase waste. Disposal impacts would also impose hefty operational and regulatory requirements and unnecessary costs merely to avoid reusing streams with low-levels of TCE byproducts. The chloromethane and EDC Streams that are reused in the PCE/CTC Reactor total several hundred million pounds annually, all of which would require thermal incineration. Additional costs associated with impacts of disposal are discussed below.

c. Negative Impacts Caused by Prohibiting Feedstock Streams that Include Low Levels of TCE Byproduct/Impurities

This section addresses the negative waste and increased upstream production impacts that a prohibition on reuse TCE as a byproduct would impose. EPA fails to consider, in the proposed rule or the Agency's own economic analysis, the negative waste and increased upstream production impacts that a prohibition on reuse TCE as a byproduct would generate. ACC urges EPA to update its economic analysis to account for real costs associated with EPA's proposed prohibition of feedstock streams that include low levels of TCE byproducts/impurities.

Increased Waste: The proposed rule's prohibition of the reuse of TCE unintentionally produced as a byproduct would stop the beneficial reuse/recycling of intermediate streams, which is counter to the Agency's own Waste Management Hierarchy that encourages reuse and recycling versus disposal or incineration. The TCE produced as a byproduct/impurity (0.1% - 7%) in the PCE/CTC reactor, or the EDC/HCl process, cannot be prevented in the production process nor removed from the stream before the reuse process. For example, if streams that include TCE produced as a byproduct cannot be processed/recycled in the PCE/CTC Reactor, then a stream totaling several hundred million pounds annually would require loading and transportation to an incinerator for destruction.

Without the ability to reuse these waste streams, manufacturers would be required to dispose of this material – primarily through thermal destruction. Existing member facilities do not have the capacity for onsite destruction of this magnitude, if at all. EPA's economic analysis does not consider the cost of off-site destruction of this material which ACC's TCE Panel estimates may total in excess of $500 million per year.[50]

Increased Make-up Volumes of Virgin Raw Material: To replace the recycled material with the TCE impurity, additional make-up volumes of raw material, *e.g.* chlorine and ethylene, would need to be produced. These replacement streams would require an increase in current production capacity to make up for the lost raw materials, along with an increase in overall production costs.

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[50] This is based on an estimate of 370 million pounds of waste streams containing byproduct TCE annually from a single chlorinated organics manufacturer. The cost includes about $300 million for thermal destruction and $200 million for transportation. The Panel's analysis does not consider the availability of incineration capacity to handle this additional material.

In addition to increased upstream production for chlorine and ethylene, the replacement material will likely not be manufactured on site and thus requiring additional transportation to the downstream production facility, resulting in an increase of emissions.

Downstream Production Impacts: Ending the processing/recycling of streams that include TCE as a byproduct in the PCE/CTC Reactor would have immediate manufacturing and downstream impacts. For example, CTC is used as a feedstock in the production of next-generation, climate-friendly refrigerants and foam blowing agents with low GWP and zero ozone-depletion potential. In addition, failure to allow TCE that is unintentionally produced in the EDC manufacturing process to be processed/recycled will also have immediate manufacturing and significant downstream impacts on the production of EDC and vinyl chloride which are used in the production of polyvinyl chloride (PVC), a critical component in the manufacture of life-saving medical solutions and for portable water and wastewater infrastructure.

d. Use of Byproduct TCE as a Reactant/Intermediate Should Not be Subject to Phaseout

As described above, prohibiting the reuse of TCE produced as a byproduct/impurity in low levels would have broad manufacturing, economic, waste, and efficiency impacts, which were not recognized in the proposal or the corresponding economic analysis. The proposed prohibition, rather than allowing compliance with a WCPP or recognizing a de minimis exception, exceeds the TSCA Section 6(a) mandates that EPA should apply requirements for addressing unreasonable risks only "to the extent necessary so that the chemical substance or mixture no longer presents such risk."

ACC's TCE Panel urges EPA to allow the ongoing reuse of TCE formed as a byproduct in the manufacture of EDC and other chlorinated materials as a reactant/intermediate indefinitely, provided owners and operators of such processes can comply with the WCPP requirements established as part of the final rule. As outlined in comments to the Agency on other risk management proposals, the exposure controls in place at chlorinated organic facilities that reuse streams with low levels of byproduct TCE have longstanding controls in place to successfully manage risk and implement compliance with the TCE WCPP.

VII. EPA Should Grant the Maximum Amount of Time for Identified COUs to Identify Viable Alternatives

a. Vapor Degreasing for Aerospace Parts and Medical Device Tubing

EPA has proposed a phaseout of TCE use for vapor degreasing of critical aerospace parts and medical device tubing after 2 years from promulgation of the regulation. Despite the brief window of allowable use, these facilities would be required to implement a WCPP to achieve the ECEL. While the Agency recognizes the critical importance of these applications and the challenge in finding effective alternatives to vapor degreasing with TCE, the regulatory alternative that EPA offers would only extend use for an additional year (3 years total). Such a short time-line does not

allow for the identification, qualification and authorization[51] of effective alternatives. To require that these facilities also implement a WCPP for only a 1 to 2 year period while also working to convert to an alternative cleaning process would present significant challenges – even for larger operations.

ACC's TCE Panel urges EPA to implement a phaseout of TCE use for vapor degreasing of aerospace parts and medical tubing over a period of 7 to 10 years, similar to the timeframes proposed for other COUs. Extending the phaseout will afford owners/operators more time for the qualification of alternative processes and allow for a more orderly transition to those processes During the phaseout period, facilities would be required to implement a WCPP.

b. Processing - Other Applications

Similar to the approach for vapor degreasing for aerospace parts and medical device tubing, EPA has proposed that the following processing uses of TCE be phased out within 2 years (3 years under the regulatory alternative) -

- polymeric microporous sheet materials,
- solvent in battery manufacture, polymer fiber spinning, fluoroelastomer and Alcantara® manufacture, and
- processing aide in caprolactam and beta-cyclodextrin manufacture.

ACC's TCE Panel urges EPA to implement a phase out of TCE use in these processing applications over a period of 7 to 10 years. Extending the phaseout will afford owners/operators more time for the qualification of alternative processes and allow for a more orderly transition to those processes. As with other COUs subject to phaseout, facilities would be required to implement a WCPP.

c. Processing – Battery Separator Manufacture

The Preamble includes a significant discussion of the information provided by battery separator manufacturers. As a result, EPA has proposed a 10-year phaseout for the use of TCE in the manufacture of battery separators. The decision is based on the determination that banning or severely restricting use of TCE for battery separator production "would disrupt the supply chain and leave the U.S. reliant on foreign suppliers to the extent that they are available to support the national economy, national security, and critical infrastructure."[52] The Preamble also discusses the unique properties of TCE that make it desirable for the particular use and the significant effort that manufacturers have made to identify viable alternatives.

Based on the information submitted to the Agency by the battery separator manufacturers, ACC's TCE Panel is concerned that the 10-year phaseout does not provide sufficient time for the

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[51] Products produced for aerospace and medical applications are generally subject to performance criteria established by the Federal Aviation Administration, the Department of Defense, or the Food and Drug Administration.

[52] 88 *Fed. Reg.* 74744.

industry to identify and implement an alternative chemistry or process. We encourage EPA to allow as long a phaseout period as reasonably possible for this important application. While we acknowledge that the Agency could take subsequent regulatory action to extend the phaseout, the potential uncertainty around such an action could result in significant market disruption.

VIII. EPA's Economic Analysis Estimates that the Costs of the Proposal Exceed the Benefits

Based on EPA's economic analysis, the costs of the Agency's proposal (and alternative proposal) are estimated to exceed the benefits by a significant amount.[53] Although TSCA Section 6(b) requires that EPA make its risk determination for a chemical "without consideration of costs or other nonrisk factors," Section 6(c) instructs the Agency to "factor in" consideration of economic consequences and the benefits of the substance in fashioning its risk management approach. This is consistent with the guidance in Executive Order 12866 that –

> Each agency shall tailor its regulations to *impose the least burden on society*, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations. (emphasis added)

Section 6(c) also instructs the Agency to consider the costs and benefits of at least one alternative regulatory action in proposing and promulgating a risk management rule. In the case of TCE, the economic impact of the regulatory alternative that EPA has identified differs only marginally from the Agency's proposal and still indicates that the costs of the controls would exceed the benefits by a factor of two to four.

The Agency's analysis is further compromised by its approach to estimating the benefits of the proposed regulation and the regulatory alternative – based on an estimate of the reduction in cancer risk. In assessing chronic risks such as cancer, the Office of Management and Budget (OMB) Circular A-4 notes that –

> It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect. . . For chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population. When a delay period between exposure to a toxin and increased probability of disease is likely (a so-called latency period), a lag between exposure reduction and reduced probability of disease is also likely. This latter period has sometimes been referred to as a "cessation lag," and it may or may not be of the same duration as the latency period.

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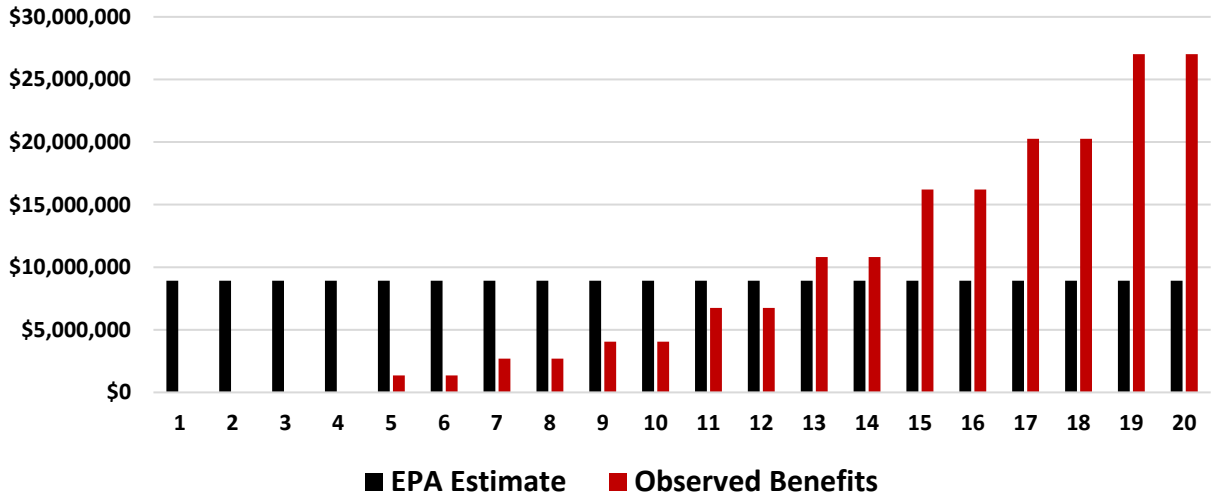
[53] USEPA. Economic Analysis of the Proposed Regulation of Trichloroethylene Under TSCA Section 6(a) (October 2023).

However, in its economic analysis, EPA monetizes reduced cancer risk from chronic exposure starting in year 1, even though the observable risk reduction will be realized only years, perhaps decades, after the rule is finalized. As EPA wrote –

> Since the benefits in each year of reduced exposure risks are estimated to be the same (for a given risk reduction measure, e.g., WCPP compliance), annualized benefits are not sensitive to the analysis timeframe.

Such an approach (based on a "micro-risk reduction") is flawed because it inflates benefits. The Agency should have created a model of risk reductions in which cancer cases arise slowly a few years after the rule is imposed, and gradually increase before reaching an asymptotic level. The Agency should have employed such a cessation lag model because it reflects risk reductions when they are observed, per OMB guidance. **Figure 1** contrasts the estimated benefits for the cessation lag and EPA's micro-risk models for EPA's risk management proposal for PCE, which demonstrates suggests that the resulting monetized value of cancer risk reduction was 66% that of EPA's inflated estimate.

Figure 1. EPA Inflated Benefits from Cancer Risk Reduction



Based on the significant issues with the current economic analysis, ACC's TCE Panel urges the Agency to consider additional regulatory alternatives that provide a less burdensome approach consistent with EO 12866 using the approach to estimate the health benefits consistent with OMB Circular A-4.

IX. Other Issues

a. EPA Should Remove the Preamble Language on Exports of TCE

In the Preamble , EPA indicates that "[a]s the manufacture and processing of TCE presents an unreasonable risk to health in the United States, the manufacture and processing of TCE for export would also be prohibited or restricted in accordance with TSCA Section 12(a)(2)."[54] Section 12(a)(2), however, does not prohibit or restrict export of a substance subject to a risk management rule under Section 6. Rather Section 12 would require that companies wishing to export TCE submit a written notice to EPA providing basic information on the exporting and importing parties, which is then forwarded to the importing party's government.

"Domestic manufacture," defined as "refer[ing] to the making or producing of a chemical substance within the United States (including manufacturing for export),"[55] is allowed pursuant to compliance with the provisions of the regulation for those COUs subjected to an extended phase-out schedule. Consistent with the clear language of TSCA Section 12, EPA should also amend the language of Section 751.305(b)(1) of the proposed regulation to read

> "all persons are prohibited from manufacturing (including <u>exporting and</u> importing) TCE, except as specified in paragraphs (b)4 through (13) of this section."

b. Establishment of a Threshold Exclusion is Essential

ACC's TCE Panel supports EPA establishing a TCE *de minimis* level to account for the impurities in the production process and in products. The Agency followed a similar approach in its recent proposed risk management rule for PCE, concluding -

> To aid the regulated community with implementing the prohibitions, and to account for de minimis levels of PCE as an impurity in products, EPA is proposing that products containing PCE at concentrations less than 0.1% by weight are not subject to the prohibitions described in this unit. EPA has determined that the prohibitions are only necessary for products containing PCE at levels equal to or greater than 0.1% by weight in order to eliminate the unreasonable risk of injury resulting from inhalation and dermal exposures from PCE-containing products during occupational and consumer conditions of use.[56]

ACC's TCE Panel urges EPA to include a similar *de minimis* provision in the current rule at the level of 0.5% account for impurities in the production process and in products. Finally, while a TCE *de minimis* level would address several feedstock streams that contain TCE as an impurity, there are some feedstock streams that contain higher concentrations of TCE. For these streams, it is critical

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[54] 88 *Fed. Reg.* at 74732

[55] Ibid, at 74726.

[56] 88 Fed. Reg. at 39652, 39671 (June 16, 2023).

that in addition to the de minimis level, the final rule allow that TCE unintentionally produced as a byproduct/impurity be allowed to continue in compliance with the WCPP.

c. EPA Should Align Its Owner or Operator Definition with OSHA Regulations

In the Preamble, EPA notes that its proposal would supplement OSHA requirements for controlling exposure to TCE. However, the Agency's definition of "owner or operator" conflicts with OSHA's requirements that are applicable to "employers," which are defined by OSHA as "a person engaged in a business affecting commerce who has employees."[57] EPA proposes the use of the term owner or operator to describe the entity responsible for implementing the controls for workplaces where an applicable condition of use is occurring and TCE is present. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.[58]

EPA's proposed definition suggests that the person or company overseeing the worksite is responsible for all aspects of managing TCE in the workplace, including providing PPE, fit testing, and worker training – regardless of whether the individual is an employee. These requirements directly conflict with OSHA compliance and enforcement policy, and present significant concerns for multi-employer workplaces or employers who have a mobile workforce. This approach, unless significant changes are implemented, will be confusing and impractical, and will create tensions between EPA rules and OSHA rules and lead to confusion and potential compliance issues. ACC's TCE Panel recommends that EPA review its requirements for owners or operators to ensure alignment with OSHA requirements.

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[57] 29 C.F.R. Section 1910.2(c).

[58] 88 *Fed. Reg.* at 74786